

# Laparoscopic Inguinal Herniorrhaphy: The New Gold Standard of Hernia Repair?

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*The surgical treatment of the common inguinal hernia has been one of the most analyzed and debated topics in medicine. Recently, with the success of laparoscopic cholecystectomy, interest in minimally invasive surgical techniques has led to its application for inguinal hernia repair. Current laparoscopic herniorrhaphies are based on the principles of conventional open preperitoneal repairs and are classified into two types: 1) transabdominal preperitoneal repair (TAPP) and 2) totally extraperitoneal repair (TEP). Common advantages to both techniques include a decrease in postoperative pain,<sup>1</sup> earlier return to normal activity,<sup>2</sup> and improved cosmesis. Both laparoscopic techniques have the disadvantage of requiring general or regional anesthesia and increased procedural costs.<sup>2</sup> Lastly, there is a concern that laparoscopic hernia repair has not been around long enough to know the risk of late recurrences. Laparoscopic herniorrhaphy, however, is a viable alternative to standard open inguinal hernia repair.*

## Introduction

Surgical treatment of the common inguinal hernia has been one of the most analyzed and debated topics in medicine. Since the earliest inguinal hernia repair described by Celsus in 50 AD to the inception of the "modern" surgical treatment of inguinal hernias in the 19th century, hundreds of different repair techniques have been described and nearly 20 different repairs are currently in use. Furthermore, it is one of the most commonly performed surgical procedures with over half a million patients a year undergoing inguinal herniorrhaphy in the United States alone. Yet despite the long and storied history of inguinal herniorrhaphy and the abundance of clinical data, no single operation has emerged as the operation of choice. In fact,

no operation in general surgery has undergone more modifications or is performed in more varying techniques than the routine inguinal repair. Until recently, however, whichever technique was used, the only way to repair an inguinal hernia, was through a relatively large incision on the abdomen. This has the major disadvantages of significant postoperative pain and prolonged disability not only due to the incision itself, but also due to the necessity of having to mobilize the cord structures and nerves in order to repair the inguinal floor. This is especially true for bilateral hernias which require incisions and dissection in both groins or recurrent hernias which require operating through the previous scar.

Recently, with the success of laparoscopic cholecystectomy, an explosion in the application of minimally invasive techniques for general surgical procedures has developed. Much of the incentive to develop these new minimally invasive techniques have been driven by patient demand, spurred on by the lay press and the Internet. Hospitals are also touting the benefits of minimally invasive surgery as a way of attracting more patients. Included in this wave of new applications are minimally invasive techniques to repair the common inguinal hernia.

## Current Laparoscopic Herniorrhaphies

The first description of a laparoscopic hernia repair was in 1989 by Ger who reported a simple ligation of the hernia sac along with closure of the fascial defect. Subsequent methods included simple mesh plugs placed in the internal ring to occlude the hernia defect or intraperitoneal onlay patches to cover the defect. These early attempts at laparoscopic repair were associated with high recurrence rates or other complications and have since been abandoned. Current laparoscopic herniorrhaphies are based on the principles of conventional open preperitoneal repairs and can be classified into two types: 1) transabdominal preperitoneal repair (TAPP) and 2) the totally extraperitoneal repair (TEP). Both techniques have their advantages and disadvantages. Common advantages to both techniques include a decrease in postoperative pain,<sup>3</sup> earlier return to normal activity, and improved cosmesis. However, unlike traditional open herniorrhaphy which can be performed under local anesthesia with sedation, both laparoscopic techniques have the disadvantage of requiring general or regional anesthesia. In addition, laparoscopic repairs are more expensive due to the need for disposable instruments, trocars and video equipment.<sup>2</sup> Lastly, many surgeons claim that neither type of laparoscopic hernia repair has been around long enough to know the risk of late recurrences.

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## Benzamycin®

(erythromycin-benzoyl peroxide topical gel)

Topical gel: erythromycin (3%), benzoyl peroxide (5%)

For Dermatological Use Only - Not for Ophthalmic Use.

Reconstitute Before Dispensing

**Brief Summary:** See full prescribing information for complete product information.

### INDICATIONS AND USAGE

BENZAMYCIN® Topical Gel is indicated for the topical treatment of acne vulgaris.

### CONTRAINDICATIONS

BENZAMYCIN® Topical Gel is contraindicated in those individuals who have shown hypersensitivity to any of its components.

### WARNINGS

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including erythromycin, and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of "antibiotic-associated colitis."

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation and treatment with an antibacterial drug clinically effective against *C. difficile* colitis.

### PRECAUTIONS

**General:** For topical use only; not for ophthalmic use. Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating or abrasive agents. If severe irritation develops, discontinue use and institute appropriate therapy.

The use of antibiotic agents may be associated with the overgrowth of nonsusceptible organisms including fungi. If this occurs, discontinue use and take appropriate measures.

Avoid contact with eyes and all mucous membranes.

**Information for Patients:** Patients using BENZAMYCIN® Topical Gel should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes, nose, mouth, and all mucous membranes.

2. This medication should not be used for any disorder other than that for which it was prescribed.

3. Patients should not use any other topical acne preparation unless otherwise directed by physician.

4. Patients should report to their physician any signs of local adverse reactions.

5. BENZAMYCIN® Topical Gel may bleach hair or colored fabric.

6. Keep product refrigerated and discard after 3 months.

### CARCINOGENESIS, MUTAGENESIS AND IMPAIRMENT OF FERTILITY

Data from a study using mice known to be highly susceptible to cancer suggests that benzoyl peroxide acts as a tumor promoter. The clinical significance of this is unknown.

No animal studies have been performed to evaluate the carcinogenic and mutagenic potential or effects on fertility of topical erythromycin. However, long-term (2-year) oral studies in rats with erythromycin ethylsuccinate and erythromycin base did not provide evidence of tumorigenicity. There was no apparent effect on male or female fertility in rats fed erythromycin (base) at levels up to 0.25% of diet.

**Pregnancy: Teratogenic Effects: Pregnancy Category C:** Animal reproduction studies have not been conducted with BENZAMYCIN® Topical Gel or benzoyl peroxide.

There was no evidence of teratogenicity or any other adverse effect on reproduction in female rats fed erythromycin base (up to 0.25% diet) prior to and during mating, during gestation and through weaning of two successive litters.

There are no well-controlled trials in pregnant women with BENZAMYCIN® Topical Gel. It also is not known whether BENZAMYCIN® Topical Gel can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. BENZAMYCIN® Topical Gel should be given to a pregnant woman only if clearly needed.

**Nursing Women:** It is not known whether BENZAMYCIN® Topical Gel is excreted in human milk after topical application.

However, erythromycin is excreted in human milk following oral and parenteral erythromycin administration. Therefore, caution should be exercised when erythromycin is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness of this product in pediatric patients below the age of 12 have not been established.

### ADVERSE REACTIONS

In controlled clinical trials, the total incidence of adverse reactions associated with the use of BENZAMYCIN® Topical Gel was approximately 3%. These were dryness and urticarial reaction.

The following additional local adverse reactions have been reported occasionally: irritation of the skin including peeling, itching, burning sensation, erythema, inflammation of the face, eyes and nose, and irritation of the eyes. Skin discoloration, oiliness and tenderness of the skin have also been reported.

### DOSAGE AND ADMINISTRATION

BENZAMYCIN® Topical Gel should be applied twice daily, morning and evening, or as directed by a physician, to affected areas after the skin is thoroughly washed, rinsed with warm water and gently patted dry.

### How Supplied and Compounding Directions:

Size (Net Weight)	NDC 0066-	Benzoyl Peroxide Gel	Active Erythromycin Powder (In Plastic Vial)	Ethyl Alcohol (70%) To Be Added
11.65 grams (as dispensed)	0510-05	10 grams	0.4 grams	1.5 mL
SAMPLE				
23.3 grams (as dispensed)	0510-23	20 grams	0.8 grams	3 mL
46.6 grams (as dispensed)	0510-46	40 grams	1.6 grams	6 mL

Prior to dispensing, tap vial until powder flows freely. Add indicated amount of ethyl alcohol (70%) to vial (to the mark) and immediately shake to completely dissolve erythromycin. Add this solution to gel and stir until homogeneous in appearance (1 to 1½ minutes). BENZAMYCIN® Topical Gel should then be stored under refrigeration. Do not freeze. Place a 3-month expiration date on the label.

**NOTE:** Prior to reconstitution, store at room temperature between 15° and 30°C (59° - 86°F).

After reconstitution, store under refrigeration between 2° and 8°C (36° - 46°F).

Do not freeze. Keep tightly closed. Keep out of the reach of children.

**Caution:** Federal (U.S.A.) law prohibits dispensing without prescription.

U.S. Patent Nos. 4,387,107 and 4,497,794

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## Transabdominal Preperitoneal Repair (TAPP)

Currently, the most popular laparoscopic technique is the TAPP repair. The procedure is performed intra-abdominally, placing a 10 mm laparoscope into the abdomen. The peritoneum just anterior to the internal ring is incised and the peritoneal surface is dissected off the abdominal wall. The pertinent anatomy is carefully exposed and a large panel of synthetic mesh is placed on the anterior abdominal wall and tacked in place to cover the hernia defects. The peritoneum is then closed over the mesh to completely cover it and separate the mesh from the intraperitoneal contents. The major advantages of the TAPP approach are that the contralateral side can easily be examined at the time of a unilateral repair and the working space is much larger, making it the easiest of the two laparoscopic repairs. The main disadvantage is that the operation is performed completely intraperitoneally, potentially exposing the intra-abdominal contents to the risks of any abdominal surgery including vascular and intestinal trocar injuries, postoperative bowel obstruction and trocar site herniation.

## Totally Extraperitoneal Repair (TEP)

Although this approach is technically the most difficult, it is perhaps the most satisfying of all laparoscopic hernia repairs developed thus far. The operation is performed according to techniques that have proven effective in open surgery. No compromises in technique are made to accomplish this repair laparoscopically. The procedure is performed by first creating a totally extraperitoneal working space using a air or water filled balloon to dissect the peritoneum off the abdominal wall and create a preperitoneal space. Once this space is created, a pneumo-preperitoneum is established using CO<sub>2</sub> gas insufflation. From this point, the operation is performed in a similar manner to the TAPP repair. The appropriate structures are identified and again a large panel of synthetic mesh is tacked into place to completely cover and reinforce the inguinal floor. Despite being the most difficult of all laparoscopic hernia repairs because of the limitation of a small working space in the preperitoneum, this operation is gaining popularity and may become the laparoscopic repair of choice. The TEP repair offers the same advantages as the TAPP repair but because it is performed totally extraperitoneally, it minimizes the risk of intra-abdominal complications. Furthermore, much of the hernia dissection is performed by the balloon during the creation of the preperitoneal space, saving operative time and simplifying the identification of the anatomy.

## Indications and Patient Selection

The first and most important criteria is that the patient be a suitable candidate for general anesthesia. Unlike open hernia repairs, laparoscopic repairs cannot be performed using local anesthesia. Although laparoscopic herniorrhaphy has been performed using regional anesthesia, most surgeons feel that additional abdominal relaxation obtained with general anesthesia is important and routinely require it for this approach. Beyond the requirement that patients be suitable medical candidates for general anesthesia, selection of patients suitable for a laparoscopic approach is a subject of controversy. The benefits of decreased postoperative pain and earlier return to activity are greatest in patients who undergo simultaneous laparoscopic repair of bilateral hernias or those who have recurrent hernias. Patients with bilateral hernias benefit because instead of the large incision in each groin necessary for open repair, both hernias can be repaired laparoscopically through the same small incisions with minimal in-

crease in postoperative pain. Furthermore, patients who have recurrent unilateral or bilateral inguinal hernias, also benefit because the laparoscopic approach avoids having to operate through scar from the previous surgery. Also, patients whose occupation or lifestyle require returning to full activity as soon as possible can also benefit from laparoscopic herniorrhaphy. Unlike open repair which leads to a 3-6 week period of disability, most surgeons allow patients to resume normal activity as soon as they feel able to. Typically, most return to normal activity within a week, although many highly motivated individuals return to strenuous physical activity in 2-3 days following surgery.

## Results

Both retrospective reviews and randomized, prospective trials have demonstrated the benefit of decreased postoperative pain and earlier return to normal activity for laparoscopic repair as compared to "tension free" open hernia repair.<sup>1,2,4</sup> Postoperative pain has been significantly less and most studies have documented that patients are more comfortable and need less analgesia postoperatively. Patients return to work sooner, and this is especially true for those patients who must return to a physically strenuous job. The incidence of recurrence compares favorably to open hernia repairs and ranges from 0.3-5.0% for TAPP repairs and 0 - 8% for TEP repairs.<sup>5,6</sup> The most common reasons for recurrences have been technical problems with placement of the mesh or missing a second hernia by not completely dissecting the direct and indirect spaces. Most reports demonstrate that the incidence of recurrence decreases as surgeons gain experience with this approach. Also, not surprisingly, large hernias, bilateral hernias and complex hernias have been associated with the highest risk of recurrences and likewise, these hernias are

best performed by surgeons experienced with the procedure.<sup>7</sup> Additional complications specific to the laparoscopic approach have been a small incidence of nerve entrapment syndromes resulting in chronic pain, trocar site hernias, and a slightly higher incidence of seromas. Lastly, the TAPP approach is associated with a 0.2% incidence of small bowel obstruction usually due to adhesions at the operative site.

## Conclusions

Laparoscopic herniorrhaphy is a viable alternative to standard open inguinal hernia repair. It is associated with less postoperative pain and a quicker return to normal activity. It has recurrence rates comparable to standard open repair and can be performed with low morbidity. For patients with bilateral or recurrent inguinal hernias or those who need to return to activity quickly, laparoscopic herniorrhaphy may be the procedure of choice.

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